K032403

OCT 27 2003

TAB 10

510(K) SUMMARY

Official Contact / Address of Manufacturing facility

Zita A. Yurko
Manager, Regulatory Affairs
Respironics Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668

Phone: 724-387-4120
Fax: 724-387-4216

Proprietary Name	SmartMonitor 2 Professional Series
Common/Usual Name	Apnea Monitor w/ Internal Oximeter
Classification Reference	21 CFR 868.2377 and 21 CFR 870.2700.
Classification	Class II
Appropriate Classification Panel	Anesthesiology and Cardiovascular Devices
Product Code	NPF – Apnea Monitor DQA –Oximeter
Predicate Devices	Respironics SmartMonitor 2 (K011597) Masimo SET Oximeter (K990966)
Reason for submission	Additional or expanded indications

Substantial Equivalence

This premarket notification submission demonstrates that the SmartMonitor 2 PS is substantially equivalent to a combination of the Respironics SmartMonitor 2 (K011597) and the Masimo SET Pulse Oximeter (K990966).

The functionality of the design of the monitor was verified through the use of design verification testing. The safety of the design will be assured by the completion of the IEC 60601-1 and 60601-2 testing. The Risk Traceability Matrix provided in Appendix B of the Risk Analysis assures that all hazards identified by the risk analysis are successfully mitigated.

This submission is seeking to extend the existing claims of the monitor to include an internal pulse oximeter.

Indications for Use

The SmartMonitor® 2 Professional Series Infant Apnea Monitor is intended for use in the continuous monitoring of respiration, heart rate, and SpO2 of infant patients in a hospital or home environment. The monitor detects and alarms for periods of central apnea, high or low heart rate, and high or low saturation.

Device Description

The SmartMonitor 2PS is a microprocessor-based, software-controlled device intended for use as an infant apnea monitoring system.

The SmartMonitor 2PS is designed to analyze and record physiologic signals (ECG, respiration, SpO2 and pulse rate) acquired from infant patients during sleep. Its primary function is to analyze the physiologic signals and generate visual and audible alarm indications upon detection of physiologic events such as central apnea, bradycardia, tachycardia, and high or low SpO2. The portable design of the device facilitates its use in a hospital or in a home environment.

ECG and respiration signals are acquired via a single transducer set attached to the patient and directly connected to the monitor. The measurement method used to derive the respiration signal is Transthoracic Impedance. SpO2 and plethysmographic pulse rate are acquired via an oximeter finger sensor. The acquired physiologic signals are classified and stored for use at a later time.

A Host PC may interface to the SmartMonitor 2PS via a direct serial connection for the purpose of downloading the monitor's previously stored data and/or retrieving the monitor's real time data.

The SmartMonitor 2PS is a compact, lightweight unit. Two front panel connectors are provided for the patient sensor input. The sensor connectors and associated sensor plugs are individually keyed to prevent improper insertion.

The SmartMonitor 2 is approximately 7.4 inches wide, 10 inches deep and 2.5 inches high. It weighs approximately 2 pounds.

The enclosure for the monitor is constructed of plastic injection molded materials. Components and assemblies are securely mounted inside. The enclosure design is resistant to the entrance of liquids and other foreign materials.

Locations for serial number plate, and necessary user notes are provided at the bottom of the unit. Refer to Tab 6 of this 510(k) for labels.

Accessories for the SmartMonitor 2PS include a patient cable, lead wires, and reusable ECG electrodes; a sensor belt to secure the sensors; a reusable oximeter finger sensor.

The functionality of the design of the monitor was verified through the use of design verification testing. The safety of the design will be assured by the completion of the IEC 60601-1 and 60601-2 testing. The Risk Traceability Matrix provided the Risk Analysis assures that all hazards identified by the risk analysis are successfully mitigated.

(End of Tab)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2003

Ms. Zita Yurko
Manager, Regulatory Affairs
Respironics, Inc.
Homecare Division
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668-8550

Re: K032403
Trade/Device Name: SmartMonitor 2PS
Regulation Number: 868.2377
Regulation Name: Apnea Monitor
Regulatory Class: II
Product Code: NPF, DQA
Dated: August 1, 2003
Received: August 4, 2003

Dear Ms. Yurko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

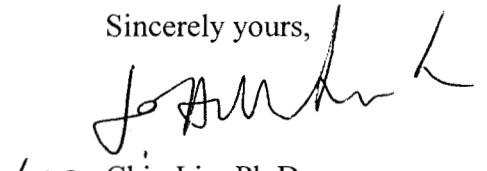
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



for, Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Center of Devices and Radiological Health

510(k) Number (if known): K032403

Device Name: SMARTMONITOR 2PS

Indications for Use:

The SmartMonitor® 2 Professional Series Infant Apnea Monitor is intended for use in the continuous monitoring of respiration, heart rate, and SpO2 of infant patients in a hospital or home environment. The monitor detects and alarms for periods of central apnea, high or low heart rate, and high or low saturation.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

prescription use ✓

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032403